Guidelines for Evaluating Guidelines

Camp Pendleton EBHC Conference

May 5, 2000

LCDR Kenneth S. Yew
Naval Hospital Jacksonville

Prostate Screening Guidelines

US Preventive Services Task Force

- Routine screening is not recommended (D)
- Those requesting screening should be given information about benefits and harms
- If screening,
  - use DRE and PSA
  - limit to men with life expectancy > 10 years

US Preventive Services Task Force , 1996.

Prostate Screening Guidelines - American Cancer Society

- Annual PSA and DRE
  - beginning at 45 for
    - African Americans
    - Family history of prostate cancer
  - beginning at 50 for all other men

American Cancer Society, 1997

Prostate Screening Guidelines

America Urological Association

- “The American Urological Association, Inc.® (AUA) endorses the American Cancer Society's policy as follows:”

  » American Urological Association, 1997.

Prostate Screening Guidelines

PSA and Digital Rectal Examination **should be offered** annually, beginning at age 50 years, to men who have at least a 10-year life expectancy .... **Information should be provided** to patients regarding **potential risks and benefits** of intervention.

American Cancer Society, 1997

"A good guideline is that if you enjoy doing something, stop doing it."

The Usefulness Equation

$$\text{Usefulness} = \frac{\text{Validity} \times \text{Relevance}}{\text{Work}}$$

Practice Guidelines - Usefulness Score

- Work: Low
  - significant potential for usefulness
- Relevance:
  - Varies between & within guidelines
- Validity:
  - Depends on the role of evidence in the guideline process

Practice Guidelines

- The Good
- The Questionable
- The Ugly

The UGLY

- Opinion based guidelines
- Consensus based guidelines

The UGLY -
Opinion based **guidelines**

- Whose opinion?
- Conflict of interest?
- Perspective?

The UGLY - Consensus based **guidelines**

- Who?
- Dominant individual?
- Time pressure?

Consensus

A process by which a group agrees to something which no individual in the group believes to be appropriate.

American Urological Association Inc.

Board of Directors, January 1992

Board of Directors, May 1992 (Reaffirmed)

Board of Directors, August 1993 (Revised)

Board of Directors, January 1994 (Revised)

Board of Directors, January 1995 (Revised)

Board of Directors, September 1997 (Revised)

The Questionable - Evidence Based **Guidelines**

- “Good Housekeeping Seal of Approval”
- How was the evidence **used**?
- POEMs vs DOEs?

American Cancer Society

- Review of all studies available
- Oncology experts reviews & recommends guidelines
- Volunteer board reviews & modifies

National Cancer Institute Mammography Guideline

Step 1 - Expert Panel Review

"The data currently available do not warrant a universal recommendation for mammography for all women in their forties. Each woman should decide for herself whether to undergo mammography . . .. Given both the importance and the complexity of the issue involved in assessing the evidence, a woman should have access to the best possible relevant information regarding both benefits and risks, presented in an understandable and usable form"

National Cancer Institute Mammography Guideline

Step 2 - Political Pressure

- Multiple letters to congressmen
- Senate vote (98 to 0) supporting mammograms for women in their 40s

National Cancer Institute Mammography Guideline

Step 3 - Advisory Board Recommendation

“All women aged 40-50 should have a mammogram every 1 to 2 years”

The Good - Evidence Linked **Guidelines**

- Exactly what is the evidence?
- How was the evidence obtained?
- How strong is the evidence for each recommendation?
- Where could you find the evidence to check it out for yourself?

The Good - Evidence Linked Guidelines

- Brief **Summary Statement** for each recommendation
- Detailed **Discussion** of the **evidence**
- Long **Reference** section pointing to **original research**
- **Methods** section showing how evidence was **obtained** and **evaluated**

Rapid Recognition of Evidence Linked Guidelines

- **Evidence Tables**
- **Strength of Evidence** Indicators
- “**Balance Sheet**”

Table 4. Estimated Likelihood Ratios for Results of PSA Testing*

Study (Reference) and PSA Level	Likelihood Ratio	
	Intracapsular Tumor	Extracapsular Tumor
Catalona et al. (70) and Brawer et al. (71)†		
<4.0 ng/mL	0.98	0.09
4.1–10 ng/mL	1.4	5.1
>10 ng/mL	0.4	49.6
Richie et al. (9)‡		
<4.0 ng/mL	0.7	0.4
≥4.1 ng/mL	3.0	4.6
Catalona et al. (140)§		
<4.0 ng/mL	0.8	0.5
4.1–10 ng/mL	2.8	3.2
>10 ng/mL	3.0‖	23.7

* Values are for likelihood of test results changing the probability

Evidence Table

- Gives citation
- Provides summary of methods and validity assessment
- Tabulates results - ARR, NNT, 95%CI
- Compares author’s and guideline team’s conclusions

Quality of Evidence

I: At least one properly randomized controlled trial.

II-1: Well-designed controlled trials without randomization.

II-2: Well-designed cohort or case-control studies, preferably from more than one center or research group.

Quality of Evidence

II-3: Multiple time series with or without the intervention.

Dramatic results in uncontrolled experiments.

III: Opinions of respected authorities.

Strength of Recommendations

A. Good evidence to support

B. Fair evidence to support

C. Insufficient evidence to recommend for or against.

D. Fair evidence to exclude

E. Good evidence to exclude

Routine Intrapartum Electronic Fetal Monitoring

	Recommendation	Evidence
Low-risk pregnancies	I	D
High-risk pregnancies	I	C

Echocardiography Guidelines

Class I: Conditions for which there is evidence and/or general agreement where a given procedure or treatment is useful and effective.

ACC/AHA Guidelines

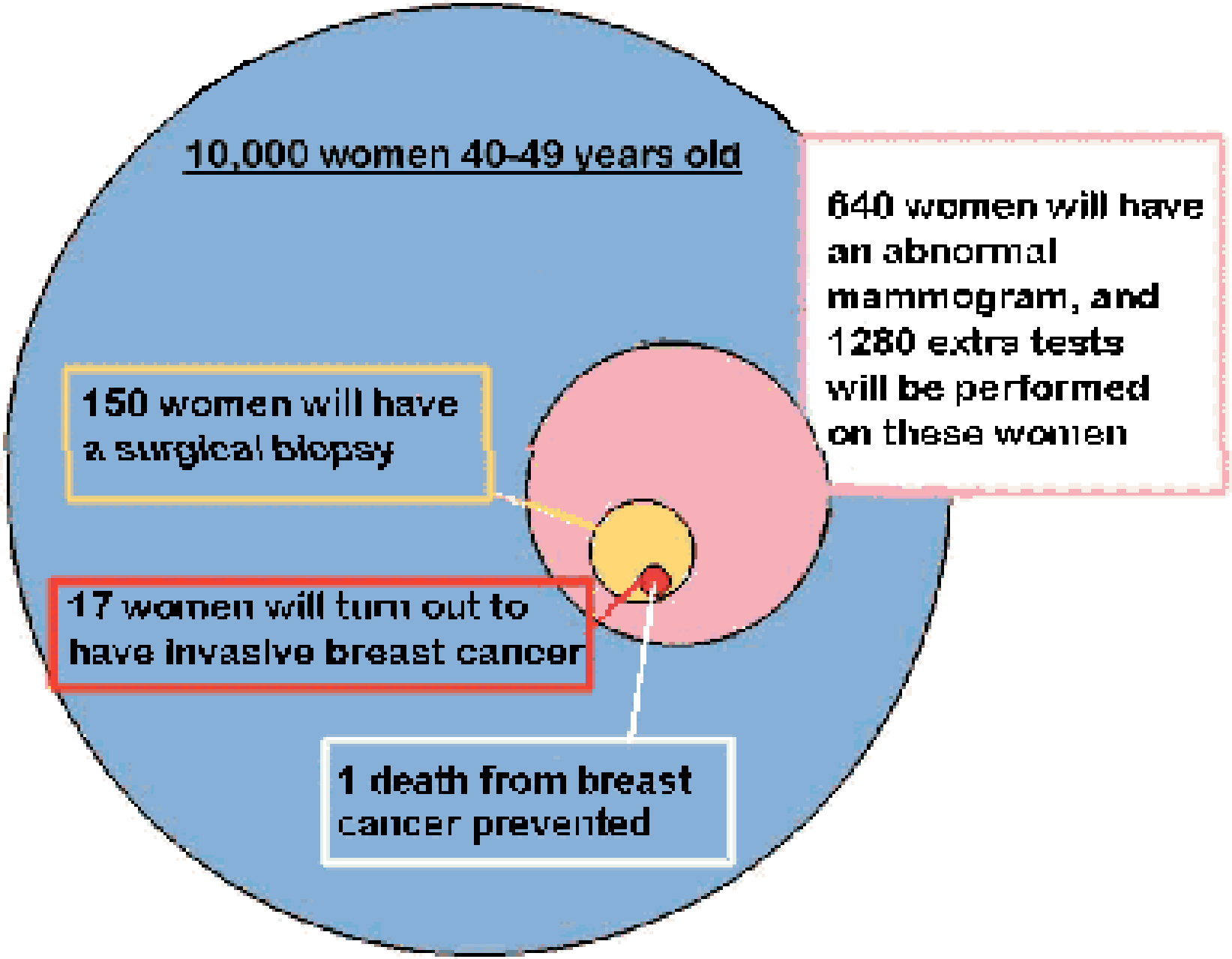
Effect	Patients with Tumor <0.5 mL (*n* = 9000)	Patients with Intracapsular Tumor >0.5 mL (*n* = 4380)	Patients with Extracapsular Tumor >0.5 mL (*n* = 1620)	All Patients (*n* = 100 000)	Amount of Life Lost or Gained	Amount of Life Affected
Estimated harm						
Cases of cancer missed by DRE, PSA measurement, and biopsy, *n*†	8778	3120	1086	12 984		
Cases of cancer detected by DRE, PSA measurement, or biopsy, *n*	222	1260	534	2016		
Patients with suspicious DRE results or PSA levels, *n*				15 000		
Patients who had transrectal ultrasonography or biopsy, *n*†				10 752		
Patients who had urinary tract infections as a result of biopsy, *n*				602		
Patients who had urosepsis as a result of biopsy, *n*				54		
Amount of life lost as a result of urosepsis, *life-years*‡					21	
Patients who had radical prostatectomy, *n*§	157	895	379	1431		
Patients who died as a result of radical prostatectomy, *n*	1	5	2	8		
Amount of life lost as a result of radical prostatectomy, *life-years*	19	110	33		162	
Amount of life affected by illness from radical prostatectomy, *life-years*						
Incontinence‖						2589
Impotence¶						13 002
Incontinence and impotence**						3884
Total amount of life harmed by screening, *life-years*††					183	19 475
Estimated maximum benefit						
Patients who survived radical prostatectomy, *n*	156	890	377	1423		
Patients with metastatic cancer that responded to hormone therapy						
Patients saved by treatment, *n*	28	379	0	407‡‡		
Amount of life affected by treatment, *life-years*	51	553	0			604
Patients with metastatic cancer refractory to hormone therapy						
Patients saved by treatment, *n*	25	337	0	367‡‡		
Amount of life affected by treatment, *life-years*	21	222	0			243
Cancer-related deaths prevented, *n*	25	339	0	364‡‡		
Amount of life gained, *y*	335	4271	0		4606	
Total amount of life that benefited from screening, *life-years*§§					4606	849

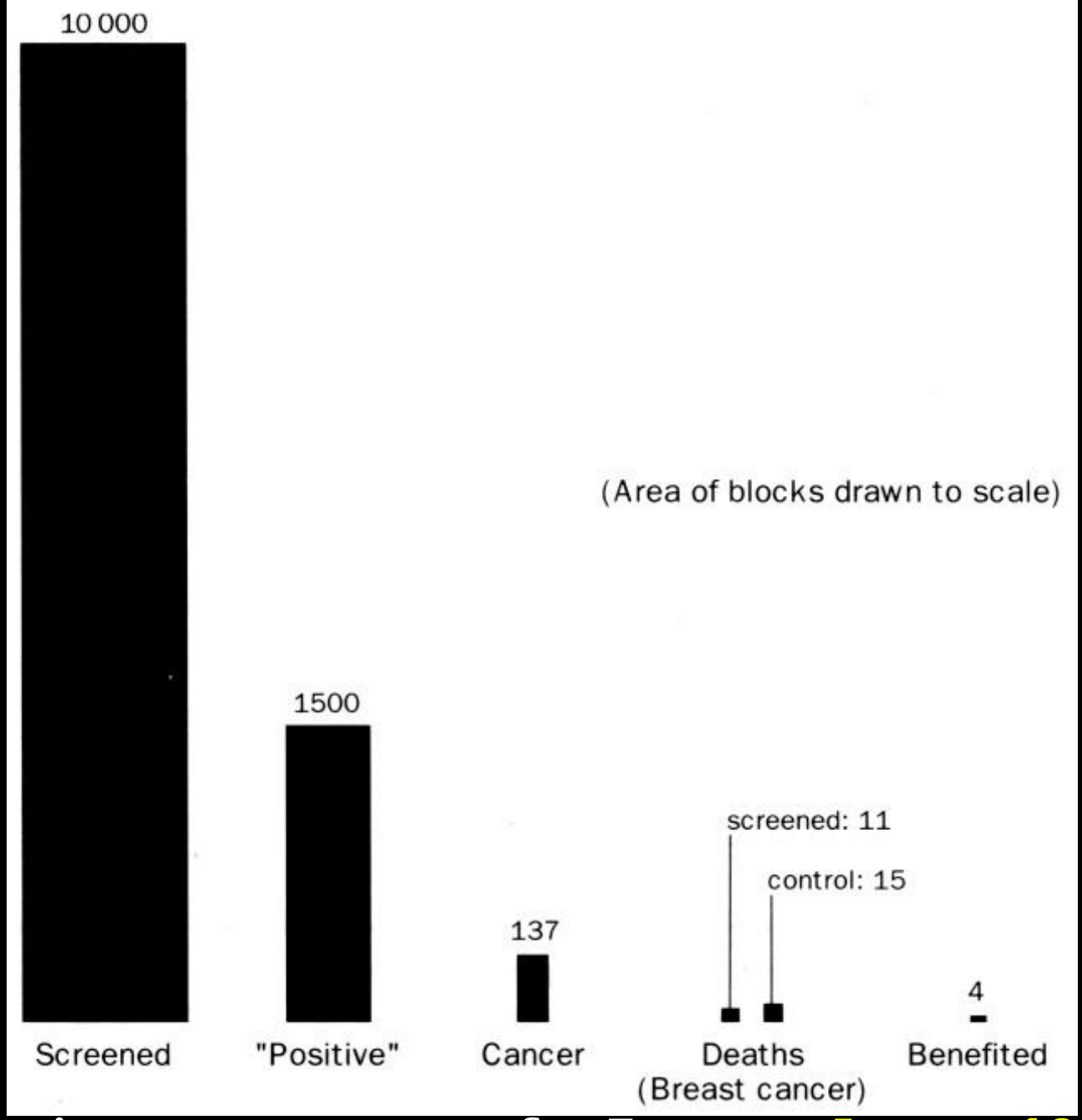
* In a cohort of 100 000 men screened for prostate cancer, no cancer would be found in 85 000. DRE = digital rectal examination; PSA = prostate-specific antigen.

Screening for Prostate Cancer
Balance Sheet - Age 50-59

Affected		Years of Life Gained or Lost
Harmed by Screening	183	19,475
Benefited by Screening	4,606	849

Ann Int Med 1997;126:468-79


10,000 women 40-49 years old
640 women will have an abnormal mammogram, and 1280 extra tests will be performed on these women
150 women will have a surgical biopsy
17 women will turn out to have invasive breast cancer
1 death from breast cancer prevented



Screening mammograms for 7 years - Lancet 1995;346:29-32

Guidelines - Validity Issues

- Explicit & sensible process to identify, select & combine evidence?
- Explicit & sensible process to assess values of different outcomes?
- Account for recent developments?
- Subjected to peer review & testing

Do the ATS Guidelines Work?

- 864 Immunocompetent Adult Outpatients
- Therapies classified as
  - consistent with guidelines
  - inconsistent with guidelines
- Followed for outcome

JAMA 1997;278:3
2-39

60 or younger
No comorbidity

Consistent	Inconsistent
Antibiotic costs $5.43	Antibiotic costs $18.51
Return to work - 7 d	Return to work - 8 d

No differences in hospitalization, rash, nausea, vomiting, diarrhea, or quality of life.

JAMA 1997;278:3
2-39

Over 60 or Comorbidity

Consistent	Inconsistent
Antibiotic cost $73.50	Antibiotic cost $7.50
Mortality rate 5.4%	Mortality rate 0.8%
Hospitalization 17.9%	Hospitalization 8.0%

No difference in days off work, rash, nausea, vomiting, diarrhea, or quality of life.

JAMA 1997;278:3
2-39

Finding the Evidence *and* a Guideline

- InfoRetriever
- SUMSearch
  - sumsearch.uthscsa.edu/searchform45.htm
  - US or Canadian guidelines plus DARE plus systematic reviews
- The TRIP Database
  - http://www.ceres.uwcm.ac.uk/frameset.cfm?section=trip

Guidelines

Tired

- Authority
- Hidden Methods
- Theoretical
- Prescriptive Guidelines

Wired

- Evidence
- Open Methods
- Tested
- Information to guide patient choice